CHAPTER 18
CENTRALIZED PRESCRIPTION FILLING AND PROCESSING

657—18.1(155A) Purpose and scope. The purpose of this chapter is to provide standards for centralized prescription drug filling or processing by a pharmacy. Any facility established for the purpose of filling or processing prescription drug orders on behalf of other pharmacies shall be licensed as a pharmacy and shall hold all necessary registrations. A hospital pharmacy shall not be authorized to participate in centralized prescription filling or processing pursuant to these rules. Except as specifically identified in the rules, the requirements of these rules for centralized prescription filling or processing are in addition to the requirements of 657—Chapters 6 and 8, and other rules of the board relating to services provided by pharmacies.

657—18.2(155A) Definitions. For the purposes of this chapter, the following definitions shall apply:

"Central fill or processing pharmacy" means a pharmacy contracting with an originating pharmacy, or having the same owner as an originating pharmacy, that provides centralized prescription drug order filling or processing on behalf of the originating pharmacy pursuant to these rules.

"Centralized prescription drug order filling or processing" or *"centralized filling or processing"* means the filling or processing of a prescription drug order by a pharmacy on behalf of another pharmacy. "Centralized filling or processing" does not include the dispensing of a prescription drug order but may include any of the following:

1. Receiving, interpreting or clarifying prescription drug orders;
2. Entering data and transferring prescription drug order information;
3. Obtaining refill and substitution authorizations.

"Dispense" means the delivery of a prescription drug or device to an ultimate user or the ultimate user's agent by or pursuant to the lawful order of a practitioner. "Dispense" includes:

1. Performing drug regimen review;
2. Interpreting clinical data for prior authorization for dispensing;
3. Performing therapeutic interventions;
4. Providing drug information concerning a patient's drug therapy;
5. Providing patient counseling.

"Hospital" means a facility licensed pursuant to Iowa Code chapter 135B.

"Hospital pharmacy" means and includes a pharmacy licensed by the board and located within any hospital, health system, institution, or establishment which maintains and operates organized facilities for the diagnosis, care, and treatment of human illnesses to which persons may or may not be admitted for overnight stay at the facility.

"Originating pharmacy" means a pharmacy that receives a prescription drug order from a patient or the patient's agent, outsources prescription filling or processing functions to another pharmacy, and ultimately dispenses the prescription drug or device to the patient or the patient's agent.

657—18.3(155A) General requirements.

18.3(1) *Essential qualifications.* A pharmacy may outsource prescription drug filling or processing to a central fill or processing pharmacy provided the pharmacies:

a. Have the same owner or have entered into a written contract or agreement that outlines the services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with federal and state laws, rules, and regulations; and

b. Share a common electronic file or have appropriate technology to allow access to sufficient information necessary or required to process a nondispensing function.

18.3(2) *Legal compliance.* A central fill or processing pharmacy shall comply with all provisions applicable to the pharmacy contained in federal and state laws, rules, and regulations to the extent applicable for the specific filling or processing activity and these rules, including:

a. Duties that must be performed by a pharmacist; and

b. Supervision requirements for pharmacy technicians.

18.3(3) *Originating pharmacy responsibility.* The originating pharmacy shall be responsible for all dispensing functions as the term "dispense" is defined in rule 18.2(155A).

18.3(4) *Label requirements.* The label affixed to the prescription container filled by a central fill or processing pharmacy on behalf of an originating pharmacy shall include the following:

a. A unique identifier indicating that the prescription was filled at the central fill or processing pharmacy;

b. Serial number (a unique identification number of the prescription) as assigned by the originating pharmacy;

c. The name, address, and telephone number of the originating pharmacy;

d. The name of the patient or, if such drug is prescribed for an animal, the species of the animal and the name of its owner;

e. The name of the prescribing practitioner;

f. The date the prescription is filled by the central fill or processing pharmacy;

g. The directions or instructions for use, including precautions to be observed;

h. Unless otherwise directed by the prescriber, the name, strength, and quantity of the drug dispensed.

(1) If a pharmacist selects an equivalent drug product for a brand name drug product prescribed by a practitioner, the prescription container label shall identify the generic drug and may identify the brand name drug for which the selection is made, such as "(generic name) Generic for (brand name product)".

(2) If a pharmacist selects a brand name drug product for a generic drug product prescribed by a practitioner, the prescription container label shall identify the brand name drug product dispensed and may identify the generic drug product ordered by the prescriber, such as "(brand name product) for (generic name)";

i. The initials or other unique identification of the pharmacist in the originating pharmacy who performed drug use review and transmitted the prescription drug order to the central fill or processing pharmacy.

657—18.4 Reserved.

657—18.5(155A) Notifications to patients.

18.5(1) *Prior notification.* A pharmacy that outsources prescription drug order filling or processing to another pharmacy shall, prior to outsourcing a patient's prescription:

a. Notify the patient or the patient's agent that prescription filling or processing may be outsourced to another pharmacy; and

b. Provide the name of the pharmacy that will be filling or processing the prescription or, if the pharmacy is part of a network of pharmacies under common ownership and any of the network pharmacies may fill or process the prescription, the patient shall be notified of this fact. Notification may be provided through a one-time written notice to the patient or patient's agent or through use of a sign prominently displayed in the originating pharmacy.

18.5(2) *Exception.* The provisions of this rule do not apply to a patient in a facility, such as a long-term care facility, where Iowa law requires that drugs be administered to the patient by a health care professional.

657—18.6 to **18.9** Reserved.

657—18.10(155A) Policy and procedures.

18.10(1) A policy and procedure manual relating to centralized filling or processing activities shall be maintained at all pharmacies involved in centralized filling or processing and shall be available for inspection and copying by the board.

18.10(2) The manual shall:

a. Outline the responsibilities of each of the pharmacies;

b. Include a list of the names, addresses, telephone numbers, and all license and registration numbers of the pharmacies involved in centralized filling or processing;

c. Include evidence that all licenses and registrations have been verified to be current and in good standing, identifying the individual verifying license and registration status and the method used to verify status; and

d. Include, but not necessarily be limited to, policies and procedures for:

(1) Protecting the confidentiality and integrity of patient information;

(2) Maintaining appropriate records to identify the name, the initials or unique identification code, and the specific activities of each pharmacist or pharmacy technician who performed any centralized filling or processing function;

(3) Complying with federal and state laws, rules, and regulations;

(4) Operating a continuous quality improvement program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems; and

(5) Reviewing, at least annually, the written policies and procedures and documenting that review.

657—18.11 to **18.14** Reserved.

657—18.15(155A) Records. Central fill or processing pharmacies shall maintain appropriate records that identify, by prescription drug order, the name and initials or unique identification code of each pharmacist or pharmacy technician who performs a centralized filling or processing function for a prescription drug order. Originating pharmacies shall maintain appropriate records that identify, by prescription drug order, the name and initials or unique identification code of the pharmacist who performed drug use review and transmitted the prescription drug order to the central fill or processing pharmacy. These records may be maintained separately by each pharmacy and pharmacist or technician or in a common electronic file as long as the data processing system is capable of producing a printout that lists the functions performed by each pharmacy and pharmacist or technician and identifies the pharmacist or technician who performed each function.

These rules are intended to implement Iowa Code sections 124.301, 124.306, 124.308, 155A.13, and 155A.28.

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